

Appl. No. 10/780,159
Reply Dated May 2, 2006
Response to Notice of Non-compliant Amendment dated April 5, 2006

AMENDMENTS TO THE CLAIMS

The following list of claims contains all of the claims that are, or ever have been, in the present application. This list will replace all other prior versions, and listings, of the claims:

Listing of claims:

1 (currently amended). A device suitable for implantation in a living being, said device comprising an at least partially crystalline polymer material, said polymer material comprising a plurality of zones having polymer molecular orientation and cross section, wherein the polymer material in at least one zone is more highly oriented than that polymer material in at least one other zone.

2 (original). The device of claim 1, wherein said polymer material comprises a resorbable polymer.

3 (original). The device of claim 2, wherein said resorbable polymer is selected from the group consisting of PLA, PGA, PGA/PLLA, DLPLA, and combinations thereof.

4 (original). The device of claim 1 further comprising additive materials selected from the group consisting of ceramics, fibrous materials, particulate materials, biologically active agents, plasticizers and combinations thereof.

5 (original). A method for the manufacture of a device suitable for implantation in a living being, said method comprising the steps of:
providing a polymer slug, barrel, die cavity tooling, and ram press, wherein said die cavity tooling defines a die shape;
placing said polymer slug between said ram press and die cavity tooling;
actuating said ram press in order to apply pressure upon said polymer slug, thereby forcing said polymer slug to conform to said die shape, wherein said polymer slug is formed into a

Appl. No. 10/780,159
Reply Dated May 2, 2006
Response to Notice of Non-compliant Amendment dated April 5, 2006

device comprising zones of variable alignment of the polymer structure, and zones of varying cross-section; and
removing said device from said die cavity tooling.

6 (original). The method of Claim 5, further comprising the step of:
machining said device to a finished product.

7 (canceled).

8 (original). The method of claim 7, wherein said heating creates a temperature gradient in said polymer slug, die cavity tooling and barrel.

9 (original). The method of claim 7, wherein prior to removing said device from said die cavity tooling, said device is reheated and allowed to cool.

10 (original). The method of claim 5, wherein said polymer slug comprises a resorbable polymer.

11 (original). The method of claim 10, wherein said resorbable polymer is selected from the group consisting of PLA, PGA, PGA/PLLA, DLPLA, and combinations thereof.

12 (original). The method of claim 5, wherein said polymer slug provided further comprises additive materials.

13 (original). The method of claim 12, wherein said additive materials are selected from the group consisting of ceramics, fibrous materials, particulate materials, biologically active agents, plasticizers and combinations thereof.

Appl. No. 10/780,159
Reply Dated May 2, 2006
Response to Notice of Non-compliant Amendment dated April 5, 2006

14 (original). The method of claim 5, wherein said die cavity tooling comprises a head portion and a shank portion, wherein said head portion has a larger cross section than said shank portion.

15 (original). The method of claim 5, wherein said die cavity tooling is temperature controlled.

16 (original). The method of claim 5, wherein said barrel is temperature controlled.

17 (original). The method of claim 5, wherein said ram press further comprises complex geometry.

18 (original). The method of claim 5, wherein said die cavity tooling is not unitary but rather comprises a plurality of pieces capable of fitting together.

19 (original). The method of claim 5, wherein said polymer slug further comprises complex geometry.

20 (original). The method of claim 5, wherein said die cavity tooling further comprises an ejection pin.

21 (original). The method of claim 20, wherein said ejection pin serves to form an end of said polymer slug.

22 (currently amended). A method for the manufacture of a device suitable for implantation in a living being, said method comprising the steps of:

a. providing a polymer slug, die cavity tooling, and ram press, wherein said die cavity tooling defines a die shape having a plurality of zones of varying cross-section, and wherein said polymer slug has a polymeric molecular structure;

Appl. No. 10/780,159
Reply Dated May 2, 2006
Response to Notice of Non-compliant Amendment dated April 5, 2006

- b. placing said polymer slug between said ram press and die cavity tooling;
- c. heating at least said polymer slug to a temperature in a range between the glass transition temperature and the melting temperature;

[[c]] d. after said heating, actuating said ram press in order to apply pressure upon said polymer slug, thereby deforming said polymer slug and forcing said polymer slug to conform to said die shape, wherein said deforming causes an alignment of said polymeric molecular structure, and further wherein at least one zone undergoes a greater degree of deformation than a different zone, thereby resulting in said polymer slug is being formed into a device comprising zones of variable alignment of the polymer molecular structure, and zones of varying cross section; and

[[d]] e. removing said device from said die cavity tooling

~~e. placing said device between said ram press and a second die cavity tooling, wherein said second die cavity tooling defines a second die shape;~~

~~f. actuating said ram press in order to apply pressure upon said device, thereby forcing said device to conform to said second die shape, wherein said device is formed into a twice pressed device comprising zones of increased alignment of the polymer structure, and zones of varying cross section.~~

23 (currently amended). A device suitable for implantation in a living being, said device comprising a polymer material having a plurality of zones of variable alignment of the polymer structure, and a plurality of zones of varying cross-section, and wherein said device is made by the process of:

- a. providing a polymer slug, die cavity tooling, and ram press, wherein said die cavity tooling defines a die shape having a plurality of zones of varying cross-section, and wherein said polymer slug has a polymeric molecular structure;

- b. placing said polymer slug between said ram press and die cavity tooling;

Appl. No. 10/780,159
Reply Dated May 2, 2006
Response to Notice of Non-compliant Amendment dated April 5, 2006

c. heating at least said polymer slug to a temperature in a range between the glass transition temperature and the melting temperature;

[[c]] d. after said heating, actuating said ram press in order to apply pressure upon said polymer slug, thereby deforming said polymer slug and forcing said polymer slug to conform to said die shape, wherein said deforming causes an alignment of said polymeric molecular structure, and further wherein at least one zone undergoes a greater degree of deformation than a different zone, thereby resulting in said polymer slug-is being formed into said device comprising zones of variable alignment of the polymer structure, and- said zones of varying cross section, and wherein said at least one zone has a greater degree of alignment than said different zone; and

[[d]] e. removing said device from said die cavity tooling.

24 (original). The device made by the process of Claim 23, the process further comprising the step of:

machining said device to a finished product.

25-27 (canceled).

28 (original). The device made by the process of Claim 23, wherein said polymer slug comprises a resorbable polymer.

29 (original). The device of claim 28, wherein said resorbable polymer is selected from the group consisting of PLA, PGA, PGA/PLLA, DLPLA, and combinations thereof.

30 (original). The device made by the process of Claim 23, wherein said polymer slug provided further comprises additive materials.

Appl. No. 10/780,159
Reply Dated May 2, 2006
Response to Notice of Non-compliant Amendment dated April 5, 2006

31 (original). The device of claim 30, wherein said additive materials are selected from the group consisting of ceramics, fibrous materials, particulate materials, biologically active agents, plasticizers and combinations thereof.

32 (original). The device made by the process of Claim 23, wherein said die cavity tooling comprises a head portion and a shank portion, wherein said head portion has a larger cross section than said shank portion.

33 (original). The device made by the process of Claim 23, wherein said die cavity tooling is temperature controlled.

34 (original). The device made by the process of Claim 23, wherein said barrel is temperature controlled.

35 (original). The device made by the process of Claim 23, wherein said ram press further comprises complex geometry.

36 (original). The device made by the process of Claim 23, wherein said die cavity tooling is not a single piece but rather comprises a plurality of pieces capable of fitting together.

37 (original). The device made by the process of Claim 23, wherein said polymer slug further comprises complex geometry.

38 (original). The device made by the process of Claim 23, wherein said die cavity tooling further comprises an ejection pin.

39 (original). The device of claim 38, wherein said ejection pin serves to form an end of said polymer slug.

Appl. No. 10/780,159
Reply Dated May 2, 2006
Response to Notice of Non-compliant Amendment dated April 5, 2006

40 (new). The device of claim 1, arranged as a bone fixation device comprising a head portion and a shank portion, wherein a cross-section on a diameter of said shank portion is smaller than a cross-section on a diameter of said head portion, and further wherein said shank portion features greater alignment of polymer molecules than said head portion.

41 (new). The method of claim 22, further comprising the steps of:

f. placing said device between said ram press and a second die cavity tooling, wherein said second die cavity tooling defines a second die shape; and

g. actuating said ram press in order to apply pressure upon said device, thereby forcing said device to conform to said second die shape, wherein said device is formed into a twice-pressed device comprising zones of increased alignment of the polymer molecular structure, and zones of varying cross section.